

Message

From: Epstein, Laura [Laura.Epstein@fda.hhs.gov]
Sent: 2/17/2017 9:07:06 PM
To: Milewski, Elizabeth [Milewski.Elizabeth@epa.gov]; Wray-Cahen, Diane - FAS [Diane.Wray-Cahen@fas.usda.gov]; Dass, Brinda [Brinda.Dass@fda.hhs.gov]; Sid Abel [Sidney.W.Abel@aphis.usda.gov]; Pearson, Alan - APHIS [Alan.Pearson@aphis.usda.gov]; Wozniak, Chris [wozniak.chris@epa.gov]
CC: Beetham, Patricia K - APHIS [Patricia.K.Beetham@aphis.usda.gov]; Blanco, Carlos A - APHIS [Carlos.A.Blanco@aphis.usda.gov]
Subject: RE: REVIEW and CLEARANCE REQUEST: GE insect BP for WTO/EU biotech case bilats
Attachments: FAS Insect biotechnology in the United States and the EU_Feb2017 for review le rn.docx

FDA comments attached.

From: Milewski, Elizabeth [mailto:Milewski.Elizabeth@epa.gov]
Sent: Friday, February 17, 2017 4:06 PM
To: Wray-Cahen, Diane - FAS; Dass, Brinda; Epstein, Laura; Sid Abel; Pearson, Alan - APHIS; Wozniak, Chris
Cc: Beetham, Patricia K - APHIS; Blanco, Carlos A - APHIS
Subject: RE: REVIEW and CLEARANCE REQUEST: GE insect BP for WTO/EU biotech case bilats

Hi, Diane. Thanks for the opportunity to comment. Chris Wozniak and I have a few comments. Please see the attached file.

From: Wray-Cahen, Diane - FAS [mailto:Diane.Wray-Cahen@fas.usda.gov]
Sent: Thursday, February 16, 2017 3:33 PM
To: Dass, Brinda <Brinda.Dass@fda.hhs.gov>; Laura Epstein (laura.epstein@fda.hhs.gov) <laura.epstein@fda.hhs.gov>; Sid Abel <Sidney.W.Abel@aphis.usda.gov>; Pearson, Alan - APHIS <Alan.Pearson@aphis.usda.gov>; Wozniak, Chris <wozniak.chris@epa.gov>; Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>
Cc: Beetham, Patricia K - APHIS <Patricia.K.Beetham@aphis.usda.gov>; Blanco, Carlos A - APHIS <Carlos.A.Blanco@aphis.usda.gov>
Subject: REVIEW and CLEARANCE REQUEST: GE insect BP for WTO/EU biotech case bilats
Importance: High

Hi All,

Attached is a briefing paper on insect biotech. It includes GE insects that fall under both FDA and APHIS purview (and I assume, soon EPA as well). Therefore, we are asking FDA, APHIS, and EPA to please review and clear the paper. Please focus on the GE insect bits that fall under your Agency's authority. I have highlighted major changes to the last BP in Yellow the for APHIS sections and in Green for the FDA sections.

This BP is for the Annual meeting between the EU and the US on the status of the WTO biotechnology case (the US/Canada/Argentina "won"). These are private bilateral discussions and have been going on since about 2008 or so. They usually focus on GE crops that the EU has not approved. The US plans to ask the EU about GE insect traits that have EU applications (i.e., Oxitec Olive fly).

If possible, we would appreciate this back with your comments and edits by **Tuesday February 21st**.

Thanks
Diane

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